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ADDRESSING THE FDA'S PERFORMANCE, EFFICIENCY, AND USE OF RESOURCES

HEARINGS

OF THE

COMMITTEE ON LABOR AND HUMAN RESOURCES UNITED STATES SENATE

ONE HUNDRED FIFTH CONGRESS

FIRST SESSION

ON

EXAMINING PROPOSALS TO REFORM THE PERFORMANCE, EFFICIENCY, AND USE OF RESOURCES OF THE FOOD AND DRUG ADMINISTRATION

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minations, some state boards are willing to reexamine the issue by requiring the submission of data already reviewed and found acceptable by FDA. In these states, brand name drug firms have attempted, and are attempting, to block the substitution of generic products at the state formularies by challenging FDA's therapeutic equivalency decisions on generic drugs. This abusive practice has further delayed the marketing of generic drugs and artifically maintains the high costs of prescription drug products.

NAPM supports legislation that would preempt state formulary boards from reconsidering the FDA "A" rating that a generic drug is therapeutically equivalent to the brand name product. Reforms should also be enacted to prohibit state formulary boards from imposing additional requirements on generic drug manufacturers.

Citizen Petitions

Separate from the ANDA approval process, firms and individuals can submit citizen petitions to FDA to exercise their right to petition the government. Brand name companies have used the citizen petition process to try to block or delay FDA approval of ANDAs. NAPM believes that the citizen petition process should take its own course, and not be used to unnecessarily slow ANDA approvals.

NAPM supports legislative reforms that would prevent FDA from delaying the approval of an ANDA that meets all regulatory and scientific standards, even though a citizen petition has been filed in an attempt to block approval of the ANDA.

SECTION 507 ANTIBIOTICS

Antibiotic drugs are currently approved by FDA under Section 507 of the Federal Food, Drug, and Cosmetic Act (FDC Act), which requires, among other things, FDA to publish regulations (commonly known as "monographs") setting forth specifications for approved products. Section 507 also requires FDA to certify each batch of an antibiotic before its release for distribution. There are no comparable monograph or batch certification requirements in Section 505, which applies to non-antibiotic drugs.

Repeal of Section 507 has been included in many of the recent FDA reform proposals, including the most recently available FDA reform proposal from the Pharmaceutical Research and Manufacturers of America (PhRMA) (January 1997). NAPM agrees that the requirements of Section 507 regarding monograph regulations and batch certification are anachronistic. However, outright repeal of Section 507 would have unintended and unwarranted consequences that would significantly delay the approval of generic antibiotics to the detriment of consumers, taxpayers, federal and state governments, and third-party insurance payors. If Section 507 were repealed, antibiotics would become subject to the burdensome exclusivity, patent certification, and automatic stay of FDA approval provisions imposed on non-antibiotic generic drugs by the Hatch-Waxman Act.

Since the enactment of Section 507 in 1945, the approval requirements for generic antibiotics have been straightforward and efficient. As a result, generic antibiotics have been widely available since the 1940s. In comparison, before the 1984 enactment of the Hatch-Waxman Act, there was no specific approval mechanism for generic non-antibiotic drugs. Before 1984, few generic non-antibiotic drugs were available to American consumers.

In enacting the Hatch-Waxman Act of 1984, Congress recognized the fundamental difference between antiobiotic drugs and non-antibiotic drugs. The Hatch-Waxman Act included several benefit trade-offs for brand name drug manufacturers in exchange for an abbreviated approval mechanism for generic non-antibiotic drug manufacturers. These benefits, which were intended to maintain the balance between the brand name and generic drug industries, include a five-year or three-year exclusive marketing period free from generic competition as a reward for product innovation. They also include a requirement that the generic applicant certify the status of patents covering the brand name product, and a 30-month automatic stay of FDA approval of the generic product in the case of certain patient infringement lawsuits brought by the brand name drug manufacturer against the generic applicant.

In enacting the Hatch-Waxman Act, Congress recognized that no trade-offs for antibiotics were needed since an abbreviated approval process had been in place for antibiotics since 1945. As a result, generic antibiotics were specifically excluded from the scope of the 1984 law. A complete repeal of Section 507—and the resulting application of all existing requirements for generic non-antibiotic drugs under Section 505 to generic antibiotics—would upset the delicate balance of the Hatch-Waxman Act created in 1984 and would represent an unintended windfall for brand name antibiotic manufacturers, at the expense of generic antibiotic manufacturers, consumers, and taxpayers.

Consistent with current pending versions of FDA reform legislation, NAPM supports repeal of the Section 507 batch certification and monograph provisions. However, if antibiotic drug products are to be regulated under Section 505, Section 505 needs further amendment to provide that the Hatch-Waxman Act's exclusivity, patent certification, and stay of FDA approval provisions would continue not to apply to antibiotic drug products. Such an amendment should also require FDA to make available antibiotic product specifications (though not in the form of regulations) within 30 days following the approval of a new brand name antibiotic to continue the availability of this critical information to facilitate the approval of generic antibiotics.

BETTER PHARMACEUTICALS FOR CHILDREN ACT

NAPM and the generic drug industry support the conduct of research to establish indications for children for all drugs. However, NAPM has two objections to the current draft of the Better Pharmaceuticals for Children Act (Act): (1) the high costs of the proposed incentives to encourage sponsors of brand name pharmaceutical products to conduct the studies (that support labeling concerning use of the drug products in children) would be borne solely by the American consumer and the generic drug industry; and, (2) the Act would not apply to off-patent medicines, which comprise 80% of the current market.

The Act would permit FDA to accept one pharmacodynamic study to satisfy the pediatric studies requirement. These studies are generally quite inexpensive, often in the $100,000 range. As a reward for conducting such studies, the sponsor of the brand name pharmaceutical product studied would receive an additional six months of marketing exclusivity, during which period no generic form of that product could be approved. For a widely marketed product, the Act could result in extra prescription drug costs of hundreds of millions of dollars during the six month exclusivity period. That reward bears no reasonable relationship to such a modest expenditure.

Essentially the same provisions would apply to both new (unapproved) products, and to approved products for which three or five year exclusive marketing periods or patents have not yet expired at the time acceptable studies are submitted to FDA. A major limitation of the Act is that it has no practical applicability to marketed products for which applicable patents and exclusivity periods have already expired. Because 80% of marketed, off-patent medicines do not carry pediatric claims, this bill misses the main target.

NAPM believes that there are better incentives available to encourage brand name sponsors to conduct pediatric studies for both new and already marketed products. NAPM suggests that consideration be given to one or more of the following:

- Tax credits and government grants to support pediatric studies.
- Partial waiver of user fees for an original NDA containing data and information supporting a pediatric indication.
- Waiver of user fees for any NDA supplement or 505(b)(2) application for a pediatric indication.
- Expediting the NDA review for any application for a pediatric indication.
- Studies conducted by the National Institutes of Health.
- FDA administrative action or a legislative provision to require drug sponsors to conduct pediatric studies. (In the preamble to a 1994 final rule [59 Fed. Reg. 64,240, 64,248 (Dec. 13, 1994)], FDA stated that it has the authority to do so. However, to date FDA has not exercised that authority.)
- A statutory provision allowing the first firm to perform the requisite study and achieve FDA approval of a pediatric labeling indication to advertise for six months that it is the only "FDA approved drug" with this indication.

PHRMA'S FDA REFORM PROPOSALS

NAPM has addressed and objected to two of the key pieces of PhRMA's January 1997 FDA reform proposal—repeal of Section 507 and the Better Pharmaceuticals for Children Act. However, NAPM generally supports many other provisions in the PhRMA legislation. In some cases, NAPM believes that PhRMA's proposals should be expanded to apply equally to generic and brand name pharmaceutical products.

NAPM supports the following PhRMA FDA reform proposals:

- Good Manufacturing Practices: NAPM supports this proposed reform that would deem all chemistry, manufacturing and controls specified in an approved drug application to comply with current good manufacturing practices. (As we understand this PhRMA provision, it would apply to both generic and brand name drugs.)